Complete Summary

GUIDELINE TITLE

Quantitative sensory testing: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology.

BIBLIOGRAPHIC SOURCE(S)

Shy ME, Frohman EM, So YT, Arezzo JC, Cornblath DR, Giuliani MJ, Kincaid JC, Ochoa JL, Parry GJ, Weimer LH. Quantitative sensory testing: report of the Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology. Neurology 2003 Mar 25;60(6):898-904. [49 references] PubMed

COMPLETE SUMMARY CONTENT

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IMPLEMENTATION OF THE GUIDELINE

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IDENTIFYING INFORMATION AND AVAILABILITY

SCOPE

DISEASE/CONDITION(S)

Conditions of sensory dysfunction for which quantitative sensory testing may have clinical utility, including:

- Diabetic neuropathy
- Small fiber sensory neuropathy
- Pain syndromes
- Toxic neuropathies
- Uremic neuropathy
- Acquired and inherited demyelinating neuropathies
- Psychogenic sensory loss and malingering

GUI DELI NE CATEGORY

Diagnosis Technology Assessment

CLINICAL SPECIALTY

Neurology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

To evaluate the clinical utility, efficacy, and safety of quantitative sensory testing

TARGET POPULATION

Patients with neurologic symptoms or those at risk of developing neurological disease who may benefit from assessment and quantification of sensory function

INTERVENTIONS AND PRACTICES CONSIDERED

Quantitative sensory testing (QST) through the use of devices that generate specific physical vibratory or thermal stimuli and those that deliver electrical impulses at specific frequencies. Devices might use the method of limits or the method of levels. Devices considered in the evidence review include:

- 1. Non-computer controlled Biothesiometer
- 2. Non-computerized Marstock device
- 3. Neurometer
- 4. Vibrameter
- 5. Computerized CASE IV device
- 6. Somedic Thermotest
- 7. Computerized TSA-2001
- 8. Vibratron II
- 9. CASE III device

MAJOR OUTCOMES CONSIDERED

- Clinical utility, effectiveness, and safety of quantitative sensory testing
- Sensitivity and specificity of quantitative sensory testing in diagnostic evaluations

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources) Hand-searches of Published Literature (Secondary Sources) Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

Data for this review were identified by searches of MEDLINE, Current Contents, and references from relevant articles published between 1975 and 2001; numerous articles were also identified through searches of the extensive files of the panel members. Search items "quantitative sensory testing," "QST," and "sensory testing" were used. Abstracts and reports from meetings were included only when they related directly to previously published work. Only English language papers were reviewed.

NUMBER OF SOURCE DOCUMENTS

Over 350 articles were reviewed and rated

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Classification of Evidence

Class I: Evidence provided by a prospective study in a broad spectrum of persons with the suspected condition, using a "gold standard" for case definition, where test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy.

Class II: Evidence provided by a prospective study of a narrow spectrum of persons with the suspected condition, or a well-designed retrospective study of a broad spectrum of persons with an established condition (by "gold standard") compared to a broad spectrum of controls, where test is applied in a blinded evaluation, enabling the assessment of appropriate tests of diagnostic accuracy.

Class III: Evidence provided by a retrospective study where either persons with the established condition or controls are of a narrow spectrum, and where test is applied in a blinded evaluation.

Class IV: Any design where test is not applied in blinded evaluation OR evidence provided by expert opinion alone or in descriptive case series (without controls).

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Articles retrieved from the literature search were reviewed and rated based on study design.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Not stated

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Translation of Evidence to Recommendations

Level A rating requires at least one convincing Class I study or at least two consistent, convincing Class II studies.

Level B rating requires at least one convincing Class II study or overwhelming Class III evidence.

Level C rating requires at least two convincing Class III studies.

Rating of Recommendation

A = established as effective, ineffective, or harmful for the given condition in the specified population.

B = probably effective, ineffective, or harmful for the given condition in the specified population.

C = possibly effective, ineffective, or harmful for the given condition in the specified population.

U = data inadequate or conflicting. Given current knowledge, treatment is unproven.

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

The document was submitted to review internally by the Therapeutic and Technology Assessment Subcommittee of the American Academy of Neurology (AAN), American Academy of Neurology member reviewers, and American Academy of Neurology Sections, and externally by the American Association of Electrodiagnostic Medicine and through the peer review process of the journal Neurology.

RECOMMENDATIONS

Definitions of the ratings of recommendations (A, B, C, U) and the classification scheme for a diagnostic article (Class I-IV) are provided at the end of the "Major Recommendations" field.

Diabetic Neuropathy

- Based on Class II evidence, quantitative sensory testing (QST) measuring vibration and thermal perception thresholds is probably an effective tool in the documentation of sensory abnormalities in patients with diabetic neuropathy (Level B recommendation).
- Based on several Class II studies, QST is probably useful in documenting changes in sensory thresholds in longitudinal evaluation of patients with diabetic neuropathy (Level B recommendation).
- Although there is data to suggest that QST abnormalities may be detectable
 in the absence of clinical evidence of neuropathy in diabetic patients, there is
 no credible prospective evidence that patients with these abnormalities will
 ultimately go on to develop clinical neuropathy. Thus, whether QST is useful
 in the detection of preclinical neuropathy is unproven (Level U
 recommendation).

Small Fiber Sensory Neuropathy

 Based on limited Class II and Class III evidence, QST is possibly useful in demonstrating thermal threshold abnormalities in patients with small fiber neuropathy (Level C recommendation). The clinical utility of demonstrating such abnormalities has yet to be fully defined.

Pain Syndromes

• Although there is limited Class II evidence to suggest that QST may be useful in demonstrating altered thresholds for pain perception in patients with various pain syndromes, the sensitivity and specificity of QST in the diagnosis of such disorders are unclear (Level U recommendation).

Toxic Neuropathies

- Based on limited Class II evidence, QST is possibly useful in demonstrating sensory abnormalities that result from chemotherapy-induced neuropathy (Level C recommendation).
- There is insufficient evidence to support the use of QST in monitoring the development of neuropathy secondary to workplace exposures (Level U recommendation).

Uremic Neuropathy

 QST is possibly useful in identifying large sensory fiber dysfunction in uremic patients on the basis of limited Class II and Class III evidence (Level C recommendation).

Acquired and Inherited Demyelinating Neuropathies

• The usefulness of QST in the diagnosis or prognosis of patients with acquired or inherited demyelinating neuropathy is unproven due to the limited Class III evidence available (Level U recommendation).

Malingering

• There is insufficient evidence to support the use of QST in the diagnosis of psychogenic sensory loss or malingering (Level U recommendation)

Legal Proceedings

 Malingering and other nonorganic factors can influence the testing results, and there is currently no reliable means to account for these factors. At this time, QST is not sufficiently established to justify utilization of this technique for the purpose of resolving medicolegal matters (Level U recommendation). Therefore, it should not be used in legal proceedings.

General Clinical Recommendations. QST has contributed and has the potential to further contribute to research of sensory dysfunction. However, its role is only established when it is used as one of several tools in the evaluation of neurologic disorders. In addition to the recommendations made earlier for specific neurologic disorders, the following general recommendations are warranted.

- QST results should not be the sole criterion utilized to diagnose structural pathology, of either a peripheral or central nervous system (CNS) origin.
- Abnormalities on QST must be interpreted in the context of a thorough neurologic examination and other appropriate testing, such as electromyography (EMG), nerve biopsy, skin biopsy, or appropriate imaging studies.
- Laboratories engaged in QST should demonstrate reproducible results on both controls and patients and only allow adequately trained personnel to perform such testing. Testing should be preceded by standardized instructions to subjects and be performed in a designated, quiet room with no distractions.

Definitions:

Rating of Recommendation

A = established as effective, ineffective, or harmful for the given condition in the specified population.

B = probably effective, ineffective, or harmful for the given condition in the specified population.

C = possibly effective, ineffective, or harmful for the given condition in the specified population.

U = data inadequate or conflicting. Given current knowledge, treatment is unproven.

Classification of Evidence

Class I: Evidence provided by a prospective study in a broad spectrum of persons with the suspected condition, using a "gold standard" for case definition, where test is applied in a blinded evaluation, and enabling the assessment of appropriate tests of diagnostic accuracy.

Class II: Evidence provided by a prospective study of a narrow spectrum of persons with the suspected condition, or a well-designed retrospective study of a broad spectrum of persons with an established condition (by "gold standard") compared to a broad spectrum of controls, where test is applied in a blinded evaluation, enabling the assessment of appropriate tests of diagnostic accuracy.

Class III: Evidence provided by a retrospective study where either persons with the established condition or controls are of a narrow spectrum, and where test is applied in a blinded evaluation.

Class IV: Any design where test is not applied in blinded evaluation OR evidence provided by expert opinion alone or in descriptive case series (without controls).

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of supporting evidence is identified and graded for each recommendation (see "Major Recommendations").

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- These guidelines may assist physicians in making appropriate clinical decisions regarding the clinical utility, efficacy, and safety of quantitative sensory testing (QST) to assess and quantify sensory function in patients with neurologic symptoms or in those at risk of developing neurological disease.
- A number of studies demonstrated that quantitative sensory testing is probably or possibly useful in identifying small or large fiber sensory abnormalities in patients with diabetic neuropathy, small fiber neuropathies, uremic neuropathies, and demyelinating neuropathy.
- Quantitative sensory testing is a potentially useful tool for measuring sensory impairment for clinical and research studies.

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Because of differences between systems, normal values from one system cannot be transposed to others. Reproducibility of results was also an important concern, and there is no consensus on how it should be defined. Guideline developers did not identify any adequately powered Class I studies demonstrating the effectiveness of quantitative sensory testing (QST) in evaluating any particular disorder.
- This statement is provided as an educational service of the American Academy of Neurology. It is based on an assessment of current scientific and clinical information. It is not intended to include all possible proper methods of care for a particular neurologic problem or all legitimate criteria for choosing to use a specific procedure. Neither is it intended to exclude any reasonable alternative methodologies. The American Academy of Neurology (AAN) recognized that specific patient care decisions are the prerogative of the patient and the physician caring for the patient, based on all of the circumstances involved.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better Living with Illness

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

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ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003 Mar 25

GUI DELI NE DEVELOPER(S)

American Academy of Neurology - Medical Specialty Society

SOURCE(S) OF FUNDING

American Academy of Neurology (AAN)

GUIDELINE COMMITTEE

Therapeutics and Technology Assessment Subcommittee of the American Academy of Neurology

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

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FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUI DELI NE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: A list of American Academy of Neurology (AAN) guidelines, along with a link to a Portable Document Format (PDF) file for this guideline, is available at the AAN Web site.

Print copies: Available from the AAN Member Services Center, (800) 879-1960, or from AAN, 1080 Montreal Avenue, St. Paul, MN 55116.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

 AAN guideline development process [online]. St. Paul (MN): American Academy of Neurology.

Electronic copies: Available from the <u>American Academy of Neurology Web site</u>.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on February 9, 2004.

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